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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,114	06/22/2001	Seung-Ho Choi	13764-007001	9054

7590 07/16/2002
Kerry A. Flynn, Esq.
Cubist Pharmaceuticals, Inc.
65 Hayden Avenue
Lexington, MA 02421

EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,114

Applicant(s)

CHOI ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1-5, 12, 14-32, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a cephalosporin, and a cationic binding agent, classified in class 514, subclass 200.
 - II. Claim 1-4, 7, 11, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a glycopeptide, and a cationic binding agent, classified in class 514, subclass 8.
 - III. Claims 1-4, 10, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a penicillin, and a cationic binding agent, classified in class 514, subclass 192.
 - IV. Claims 1-4, 9, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a monobactam, and a cationic binding agent, classified in class 514, subclass 183.
 - V. Claims 1-4, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, an oxazolidinone, and a cationic binding agent, classified in class 514, subclass 340.
 - VI. Claims 1-4, 13-21, 23-29, and 33-41, drawn to pharmaceutical compositions comprising a biopolymer, a lipopeptide, and a cationic binding agent, classified in class 514, subclass 8.

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- VII. Claims 1-4, 8, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a carbapenem, and a cationic binding agent, classified in class 514, subclass 183.
- VIII. Claims 1-4, 6, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, an aminoglycoside, and a cationic binding agent, classified in class 514, subclass 25.
- IX. Claims 1-4, 14-21, 23-29, and 34-41, drawn to pharmaceutical compositions comprising a biopolymer, a β -lactamase inhibitor, and a cationic binding agent, classified in class 514, subclass 200.

For each of inventions I-IX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-IX and one of inventions (A)- (D).

- (A) The invention of the elected Group wherein the cationic agent is a cationic polymer;
- (B) The invention of the elected Group wherein the cationic agent is a metal cation;
- (C) The invention of the elected Group wherein the cationic agent is a basic amino acid; or
- (D) The invention of the elected Group wherein the cationic agent is an ammonium salt, including quaternary ammonium salts.

The inventions are distinct, each from the others, for the following reasons:

- 2. The inventions of Groups I-IX are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. See MPEP § 806.05(d). In the instant case, each Group of inventions has the same separate utility as the potential combinations. Each of the Groups is a useful pharmaceutical comprising a different type of anti-microbial ingredient from the other

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subcombinations. As each of these compositions comprises a separate anti-microbial agent, each with a different structure and a different mode of operation, the subcombinations comprising them are likewise distinct.

3. The inventions of Groups (A)-(D) are related as subcombinations disclosed as usable together in a single combination. See MPEP § 806.05(d). The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each of the Groups comprises inventions with the same separate utility as the combinations. In each Group, the composition is composed of a different type of cationic binding agent. These different binding agents have different structures and therefore have different modes of operation. The inventions comprising these different cationic agents are therefore distinct.

Election of Species

4. Each of the above Groups of inventions described above contains multiple patentably distinct species of the claimed invention: inventions wherein the pharmaceutical composition comprises one of the following biopolymers:

- a. carrageenan;
- b. xylan;
- c. chitin;
- d. chitosan;
- e. chondroitin sulfate;
- f. sodium alginate;
- g. carboxymethylcellulose;
- h. pectin;
- i. polysaccharide;
- j. polypropylene glycol;
- k. polyethylene glycol;
- l. polyacetate;
- m. liposome;

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- n. fatty acid complex;
- o. cyclodextrin;
- p. cycloamylose;
- q. clathrate;
- r. cycloalkyl amylose;
- s. polyxylose; or
- t. polylactic acid

Further, each of Groups I, II, III, IV, VII, and VIII also contain multiple patentably distinct species of the claimed invention:

If Group I is elected, the applicant must elect one of the 13 species set forth in Claim 5 as filed.

If Group II is elected, the applicant must elect one of the 3 species set forth in Claim 7 as filed.

If Group III is elected, the applicant must elect one of the 2 species set forth in Claim 10 as filed.

If Group IV is elected, the applicant must elect one of the 2 species set forth in Claim 9 as filed.

If Group VII is elected, the applicant must elect one of the 6 species set forth in Claim 8 as filed.

If Group VIII is elected, the applicant must elect one of the 6 species set forth in Claim 6 as filed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

5. Because these inventions are distinct for the reasons given above, have different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


L. Lucas
Patent Examiner
July 5, 2002


JAMES HOUSEL 7/15/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600